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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,781

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Rolf Muller

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BACHMAN & LAPOINTE, P.C.

900 CHAPEL STREET

SUITE 1201

NEW HAVEN, CT 06510

EXAMINER

ANDERSON, JERRY W

ART UNIT

PAPER NUMBER

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DELIVERY MODE

11/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,781	<b>Applicant(s)</b> MULLER ET AL.	
	<b>Examiner</b> JERRY W. ANDERSON	<b>Art Unit</b> 4152	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/06/2008</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Specification*

1. The use of the trademarks i.e. NOVELOSE, ACTISTAR CRYSTALEAN etc. Has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 4, 8, 9 and 10** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. **Regarding Claim 4**, the term “swelling level” renders the claim indefinite because the degree of swelling depends on the composition of any of the many different possible swelling liquids that may be utilized, environmental factors, and the measurement method. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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5. **Regarding Claim 8**, the term “if necessary” renders the claim indefinite because one would not know under what circumstances the steps of “partially gelatinized or at least partially plasticized” are insufficient to create “a slowly digestible starch product”.

6. **Regarding Claim 9**, the phrase “at least one additive, in particular” renders the claim indefinite because the claim may include elements not actually disclosed, thereby rendering the scope of the claim unascertainable and because it is unclear if the limitation following “in particular” is or is not part of the scope of the claim. See MPEP § 2173.05(d).

7. **Regarding Claim 10**, the phrases “in particular”, “food per se” and “and the like” renders the claim indefinite because one would not know what is or is not included in these limitations; even in light of the specification one would not know the scope of this claim.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1-8 and 10** are rejected under 35 U.S.C. 102(b) as being anticipated by Y-C. Shi, U.S. Pat. # 6,890,571.

10. **Regarding Claims 1 and 2**, the Applicant claims a slow digestible starch product, with a swellable network, crystallites and an initial hydrolysis rate of <300 %/h. Shi teaches a resistant, gelatinized, crystallized starch, (lines 6-9 col. 3, lines 34-35, 46-

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48 col. 4, *Shi*) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, ( line 13-15 col. 1 *Shi*) The applicant determines the hydrolysis rate by measuring the amount of undigested starch at intervals of .5, 1, 2, 3, 4, 5, and 6 hours and calculating the digested portion of the starch. This data is shown in Table 1 and plotted in Figures 1, 2, and 3. (Applicant's specification) Applicant states that *Shi*'s data from PGPub 2003/0219520 ( U.S. Pat. # 6,890,571) is comparable to amylase treated cornstarch, with a  $H_0$  of 200 %/hr and a  $H_c$  of 200 %/hr (pg 46, Table 1, Applicant)

11. **Regarding Claim 3, Applicant** claims a portion of the starch product greater than 20% is hydrolyzed (digested) at a constant rate. *Shi* in Table 1 lists values of SDS slowly digestible starch of 22-26 %, and that all samples contained more than 20 % said slowly digestible starch. (line 44 col. 8 Table 1, *Shi*)

12. **Regarding Claim 5, ,** *Shi* discloses the claimed invention, as discussed above, including the DSC melting point of at least 70 deg. C. (lines 50-53 col. 4 *Shi*)

13. **Regarding Claims 6 and 10,** Applicant claims a starch product containing less than 50 % resistant starch, and further that the starch product is added to a food as an ingredient. *Shi* discloses in Example 3 a food product (crackers) made using 39 % resistant starch and the results thereof in Table 3. (lines 20-45 col.9, Table 3 *Shi*)

14. **Regarding Claim 7,** Applicant claims the starch product contains 1-95 % short chain amylose in network linked crystalline of short chain amylose and basic starch. *Shi* discloses that the starch is greater than 90 % debranched, (lines 45-50 *Shi*), is highly

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crystalline, (line 46 col. 4 *Shi*) and that further steps to purify the solution may be used if necessary. (lines 23-33 col. 4 *Shi*)

15. **Regarding Claim 8**, *Shi* discloses, as discussed above, a process of manufacturing a slowly digestible starch product, gelatinized, containing short chain amylose, conditioned to set the starch network, (lines 46-49 col. 4 *Shi*) with an initial hydrolysis rate of less than 300 %/h. (pg 46, Table 1, Applicant)

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Y-C. *Shi*, U.S. Pat. # 6,890,571 in view of. *Haralampu*, S. G, U.S. Pat. # 5,849,090.

19. **Regarding claim 9**, *Shi* discloses the claimed invention, as discussed above, but lacks the use of an additive. *Haralampu* discloses the use of additives to change the

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functional properties of the resistant starch. (lines 33-43 col. 2, lines 5-19 col. 6

*Haralampu*)

20. *Shi* and *Haralampu* are analogous art in that both are concerned with the modification of starches to form a slowly digestible starch.

21. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the methods of *Shi* to produce food items useful in controlling glycemic plasma responses, (lines 36-37 col. 1 *Haralampu*), to produce physiological benefits of fiber, such as increased fecal bulk, and increased excretion of butyrate and acetate in the colon. (lines 25-28 col1 *Haralampu*).

### **Conclusion**

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY W. ANDERSON whose telephone number is (571)270-3734. The examiner can normally be reached on 7 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached at 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jwa

/Joseph S. Del Sole/  
Supervisory Patent Examiner, Art Unit 4152